

Attorney Docket No.: DEX-0199
Inventors: Salceda et al.
Serial No.: 09/817,318
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REMARKS

Claims 1-25 are pending in the instant application. The Examiner has subjected these claims to a Restriction Requirement as follows:

Groups 1-20, claims 1-6, 9 and 23, drawn to a polynucleotide of SEQ ID NOs: 1-20, an antisense, a vector, a host cell, a method of producing a mammary gland cancer specific or MSG polypeptide, a method for producing a cell expressing a MSG polypeptide;

Group 21-40, claims 7, 9 and 23, drawn to a polypeptide encoded by a polynucleotide of SEQ ID NO:1-20;

Groups 41-60, claim 8, drawn to an antibody specific for a polypeptide encoded by a polynucleotide of SEQ ID NO:1-20;

Groups 61-80, claim 10, drawn to a method for diagnosis of cancer, comprising detecting the levels of a MSG polynucleotide of SEQ ID NOs: 1-20;

Groups 81-100, claim 10, drawn to a method for diagnosis of cancer, comprising detecting the level of a polypeptide encoded by a MSG polynucleotide of SEQ ID NO:1-20;

Groups 101-120, claims 11 and 13, drawn to a method for diagnosis of metastasis or onset of mammary gland cancer comprising detecting the levels of a MSG polynucleotide of SEQ ID

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NOS: 1-20;

Groups 121-140, claims 11 and 13, drawn to a method for diagnosis of metastasis or onset of mammary gland cancer comprising detecting the levels of a polypeptide encoded by a MSG polynucleotide of SEQ ID NOS: 1-20;

Groups 141-160, claims 12 and 14, drawn to a method for staging mammary gland cancer, or monitoring changes in stages of mammary gland cancer, comprising detecting the level of a MSG polynucleotide of SEQ ID NOS: 1-20;

Groups 161-180, claims 12 and 14, drawn to a method for staging mammary gland cancer, or monitoring changes in stages of mammary gland cancer, comprising detecting the level of a polypeptide encoded by a MSG polynucleotide of SEQ ID NOS: 1-20;

Groups 181-200, claim 15, drawn to a method for identifying compounds that bind MSG polynucleotide of SEQ ID NOS: 1-20;

Groups 201-220, claim 15, 20, drawn to a method for identifying compounds that bind to or antagonize or agonize a polypeptide encoded by a MSG polynucleotide of SEQ ID NOS: 1-20;

Groups 221-240; claims 16-17, drawn to a method of imaging mammary gland cancer in a patient, comprising administering to the patient an antibody specific for a polypeptide encoded by a polynucleotide of SEQ ID NOS: 1-20;

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Groups 241-260, claims 18-19, drawn to a method for treating mammary gland cancer in a patient, comprising administering to the patient an antibody specific for a polypeptide encoded by a polynucleotide of SEQ ID NO:1-20;

Groups 261-280; claims 21 and 22, drawn to an agonist or antagonist of a polypeptide encoded by a polynucleotide of SEQ ID NOs: 1-20;

Groups 281-300, claims 24-25, drawn to a method for inducing an immune response or treating mammary gland cancer, comprising administering a MSG polynucleotide of SEQ ID NOs:1-20;

Groups 301-320, claims 24-25, claims 24-25, drawn to a method for inducing an immune response or treating mammary gland cancer, comprising administering a polypeptide encoded by a MSG polynucleotide of SEQ ID NOs:1-20.

With respect to the polynucleotide of SEQ ID NOs: 1-20 and the polypeptides encoded thereby, the Examiner suggests that each constitutes a single invention, and not a species.

The Examiner also suggest that:

upon election of any of groups 101-140, further election of the patentably distinct species, namely metastasis or onset of metastasis, is required;

upon election of any of groups 141-180, further election of

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the patentably distinct species, namely staging or detection of change in stage of mammary gland cancer, is required;

upon election of any of groups 201-220, further election of the patentably distinct species, namely compounds that bind to a MSG polypeptide, compounds that antagonize a MSG polypeptide, or compounds that agonize a MSG polypeptide, is required;

upon election of any of groups 261-280, further election of the patentably distinct species, namely agonist or antagonist, is required;

The Examiner has acknowledged that groups 1-60, 261-280 and 61-260, 281-320 are related as product and process of use, but suggests that they are distinct because the polypeptides can be used for other purposes. The Examiner also suggests that the products of groups 1-60 and 261-280 are patentably distinct because they are drawn to entirely different biochemicals having different structures, properties and activities. The Examiner also suggests that the methods of groups 61-260, 281-320 are distinct from each other because they differ at least in objectives, methods steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Applicants respectfully traverse this requirement.

MPEP §803 provides two criteria which must be met for a

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restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A proper search of the prior art relating to the MSG polynucleotides of Group I should also reveal art relating to the polypeptides encoded thereby and uses thereof as set forth in the claims of Groups III through VII. Thus, it does not appear that a serious burden would be placed upon the Examiner if restriction were not made.

Further, the Examiner has provided no evidence whatsoever in this Restriction Requirements to support the contention that the Groups have acquired separate status in the art. While the words "class" and "subclass" are included in some of the groups defined by the Examiner, the numbers, which when different, can be suggestive of a separate status in the art, have been left blank.

Accordingly, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, it is respectfully requested that this Restriction Requirement be withdrawn.

Applicants also respectfully disagree with the Examiner's characterization of the polynucleotides of SEQ ID NO:1-20 as separate inventions rather than species. In accordance with MPEP

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§806.04(f), for claims to be restricted to different species, the claims must be generally exclusive. The general test as set forth in MPEP §806.04(f) is that one claim recites limitations which under the disclosure are found in a first species but not in a second species, while a second claim recites limitations disclosed only for the second species and not the first. In the instant application, however, there are no claims reciting limitations for only one polynucleotide or polypeptide encoded thereby and not for another. Accordingly, restriction to one of the polynucleotide of SEQ ID NO:1-20 is improper as the polynucleotides are related species under the instant disclosure subjectable to a species election requirement.

In accordance with MPEP § 808.01, an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case, however, the claims are not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only 20 sequences are set forth. Accordingly, reconsideration of any species election requirement to polynucleotides of SEQ ID NO:1-20 is also respectfully requested.

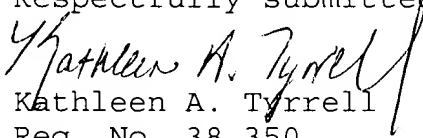
However, in an earnest effort to be completely responsive,

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Applicants elect to prosecute Group 1, SEQ ID NO:1, with traverse.

Since Applicants have elected Group 1, with traverse, no species election as set forth by the Examiner is required.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

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